

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Medicare
7500 Security Boulevard, Mail Stop C4-21-26
Baltimore, Maryland 21244-1850



MEDICARE DRUG & HEALTH PLAN CONTRACT ADMINISTRATION GROUP

DATE: February 23, 2012

TO: PACE Organizations

FROM: Danielle R. Moon, J.D., M.P.A.
Director

SUBJECT: Updated Instructions for Submitting Waiver Requests in the PACE Program

Attached are updated instructions for submitting Benefits Improvement and Protection (BIPA) waivers in the PACE program. The requirements for submitting a waiver in the PACE program have not changed, but we have consolidated both sets of instructions – for the PACE and State Administering Agency – into one document. We have also updated the forwarding instructions.

If you have any questions concerning this guidance, please contact John Hebb at 410-786-6657, or via email at John.Hebb@cms.hhs.gov.

Instructions for Submitting Waiver Requests in the PACE Program

I. Background:

Section 903 of the Benefits Improvement and Protection Act (BIPA) of 2000 addresses flexibility in exercising the waiver authority provided under sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Social Security Act. Section 903 allows for specific modifications or waivers of certain regulatory provisions to meet the needs of PACE organizations (PO). Accordingly, the Centers for Medicare & Medicaid Services (CMS) has established a process for submission and approval of waiver requests. CMS' 2002 interim final rule amended its 1999 interim final rule by adding § 460.26, which specifies the requirements for submission and evaluation of waiver requests and § 460.28, which addresses requirements related to CMS review of waiver requests. In the 2002 interim final rule, CMS removed the restrictive waiver provisions for rural and Tribal organizations.

Please note, in accordance with 42 CFR § 460.26 (c)(1-5), the following provisions may not be waived:

- 1) A focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility;
- 2) The delivery of comprehensive, integrated acute and long-term care services;
- 3) An interdisciplinary team approach to care management and service delivery;
- 4) Capitated, integrated financing that allows the provider to pool payments received from public and private programs and individuals; and
- 5) The assumption by the provider of full financial risk.

II. Instructions to PACE Organizations for Preparing and Submitting Waiver Requests to State Administering Agency (SAA)

Section 903 BIPA waiver requests may be submitted to your SAA under either of the following situations:

- 1) BIPA waiver request accompanying an application; or
- 2) BIPA waiver request independent of an application.

CMS advises PACE organizations to engage in a dialogue with the SAA regarding considerations for BIPA waiver requests prior to preparing formal requests. This will help to ensure mutual understanding of State laws and agreement among parties involved, preventing unnecessary work on the part of the PACE organization.

Any PACE organization that identifies the need for a section 903 BIPA waiver should include the following information in their waiver submission package:

- 1) Identification that the submitted document is a waiver request;
- 2) Identification of the regulatory section the PACE organization is requesting to have waived;
- 3) Rationale behind the waiver request;
- 4) If applicable, process(es), policies and procedures that will be followed to ensure participant care is not compromised;
- 5) A PACE organization point of contact for waiver; and
- 6) Identification as to whether the issue was previously submitted as a section 902 BIPA waiver grandfathering request or if it is a new request under section 903 of the BIPA.

Your SAA will forward your waiver request (one (1) hard copy and one (1) CD ROM) to the CMS Regional Office and (one (1) hard copy and one (1) CD ROM) to CMS Central Office.

Waiver requests submitted in conjunction with PACE applications must be marked as separate documents by placing them in a separate envelope labeled "waiver request." BIPA waiver requests submitted independent of an application, as stand-alone documents, must also be clearly labeled and identified as "waiver request."

Waiver requests must be submitted to your SAA, which will then review the request and forward it to CMS with any comments or concerns. CMS will arrive at a determination within ninety (90) days of the receipt of the waiver request in the Medicare Drug & Health Plan Contract Administration Group (MCAG) within CMS Central Office.

For additional details regarding the submission and evaluation of waiver requests, please refer to 42 CFR § 460.26 and 42 CFR § 460.28.

III. Instructions to State Administering Agencies for Submitting Waiver Requests

PACE organization waiver requests, along with any concerns or conditions, must be submitted to the Centers for Medicare & Medicaid Services (CMS) Central Office and applicable CMS Regional Office (RO) by the SAA.

Section 903 of BIPA requires CMS to make a determination within ninety (90) days from the date of receipt. The 90-day clock begins upon receipt of the waiver request in the Medicare Drug & Health Plan Contract Administration Group (MCAG), Division of Medicare Advantage Operations (DMAO) within CMS Central Office. Your assistance in forwarding these requests to both CMS Central and Regional Offices will help to facilitate timely processing of requests.

As noted above, Section 903 waiver requests submitted to CMS may be submitted with a PACE application, or independent of an application. Instructions for forwarding the request to CMS in either situation are defined further below:

Situation 1-BIPA Waiver Request Accompanying an Application: Waiver requests must be prepared and marked as separate documents. Requests will be reviewed simultaneously and in conjunction with the application. Please abide by the following guidelines when submitting waiver requests, which accompany applications:

- 1) Forward the program application (include five (5) hardcopies plus two (2) CD ROMs), the accompanying waiver request, and any concerns or conditions to:

Centers for Medicare & Medicaid Services
Medicare Drug & Health Plan Contract Administration Group
Attn: Jack Healey
Mail Stop C4-21-26
7500 Security Boulevard
Baltimore, Maryland 21244

- 2) Forward the program application (include two (2) hard copies and one (1) CD ROM), the accompanying waiver request, and any concerns or conditions to the applicable CMS Regional Office; and
- 3) Forward a separate copy of the waiver request and any concerns or conditions (include one (1) hard copy and one (1) CD ROM) to the attention of John Hebb at address above.

Situation 2-BIPA Waiver Request Independent of an Application: Carefully follow the guidance when submitting waiver requests inclusive of:

- 1) Forward the waiver request and any concerns or conditions (include 1 (one) hard copy and 1 (one) CD ROM) to the applicable CMS Regional Office; and
- 2) Forward the waiver request and any concerns or conditions to (include 1 (one) hard copy and 1 (one) CD ROM) to:

The Centers for Medicare & Medicaid Services
Medicare Drug & Health Plan Contract Administration Group
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